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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,561	10/22/2001	Yoshio Jo	763-29	3304

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 09/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,561	Applicant(s) JO ET AL.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20, 23, and 29* is/are rejected.

7)☒ Claim(s) *1-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claims 1-33 are objected to because of the following informalities: The examiner considers the use of the phrase "What is claimed is" that begins each claim to be inconsistent with the present Office practice. See MPEP § 608.01(m). The applicant is respectfully requested to delete this phrase from all claims and use it only once, at the beginning of the list of claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 20 and 23, the parenthetical term (etherification degree) renders the claim indefinite because it is unclear whether the term presents limitations that are part of the claimed invention. See MPEP § 2173.05

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Soe *et al.* (U.S. Patent No. 6,200,587 B1)

The Soe *et al.* patent teaches a tissue sealant that comprises carboxymethyl cellulose, with a degree of etherification of preferably 0.5% to 1.5% and most preferably 0.6% to 0.8% (See Column 3, Lines 24-38). The sealant preferably further comprises enzymes such as thrombin, and proteins which include fibrinogen and coagulation factor XIII (See Column 3, Lines 17-23; and Column 5, Lines 27-42). A method of preparing the tissue sealant is disclosed (See Column 6, Preparation Example 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.*

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Soe *et al.* patent teaches a tissue sealant that comprises carboxymethyl cellulose, with a degree of etherification of preferably 0.5% to 1.5% and most preferably 0.6% to 0.8% (See Column 3, Lines 24-38). The sealant preferably further comprises enzymes such as thrombin, and proteins which include fibrinogen and coagulation factor XIII (See Column 3, Lines 17-23; and Column 5, Lines 27-42). A method of preparing the tissue sealant is disclosed (See Column 6, Preparation Example 2). Regarding Claims 3-6 and 9-19, it is the position of the examiner that the patentability of these product-by-process claims does not depend on the method of production. The burden therefore shifts to the examiner to show an unobvious difference of the invention of these claims over the prior art. See MPEP § 2113

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.* in view of Edwardson *et al.* (U.S. Patent No. 5,962,026)

Soe *et al.* does not teach the chemical bonding of proteins to cellulosic fibers through treatment with carbodiimide.

The Edwardson *et al.* patent teaches a fibrin composition useful as a surgical sealant to provide hemostasis (See Abstract). The patent discloses that a thrombin-like enzyme may be immobilized on a support through various activation chemistries, including carbodiimide groups. Suitable supports for immobilization include cellulose and cellulose derivatives (See Column 8, Line 63 to Column 9, Line 35).

It would be obvious to one of ordinary skill in the art to combine the teachings of Soe *et al.* and Edwardson *et al.* into the objects of Claims 7 and 8. Edwardson *et al.* provides a motivation, disclosing that immobilization of a thrombin-like enzyme can prevent contamination of the composition (See Column 8, Lines 57-62). Alternatively, as stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art.

Claims 20, 23, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.* and Edwardson *et al.* in view of Waldeck (U.S. Patent No. 2,510,355) and Onda *et al.* (U.S. Patent No. 4,091,205)

The combined teachings of Soe *et al.* and Edwardson *et al.* do not disclose steps for the etherification of low-substituted cellulose.

The Waldeck patent teaches methods of the manufacture of carboxymethyl cellulose. A preferable form of the etherification process disclosed in the patent involves spraying dilute chloracetic acid onto a reaction mixture comprising cellulose and sodium hydroxide. An alternate process involves spraying a sodium chloracetate solution on the reaction mixture in place of the chloracetic acid (See Column 3, Lines 38-50). An example is given in which cellulose is sprayed with a sodium hydroxide solution and tumbled for a total of 3 hours. This mixture was then reacted with a sodium chloracetic solution for a total of four hours, then with sodium bicarbonate. The reaction product was then dried (See Column 6, Example 3; and Figure). The etherification process disclosed in the patent may take from 3 to 8 hours (See Column 2, Lines 24-28).

The Onda *et al.* patent teaches methods for preparing low-substituted cellulose ethers, useful for having an excellent binding force and sufficient disintegrating ability (See Abstract; and Column 1, Lines 6-10). The disclosed method of preparation produces cellulose ethers with a low degree of molar substitution, such as from 0.05 to 1.0 (See Column 2, Lines 5-10). Among the cellulose ethers that may be produced by this method is carboxymethylcellulose (See Column 3, Line 44). The novelty of the disclosed method deals primarily with the neutralization process in the preparation of cellulose ethers (See Column 2, Line 46 to Column 3, Line 19). Other steps may be carried out according to known and conventional methods, including etherification, washing, dehydration, drying, and pulverization (See Column 2, Lines 26-42; and Column 3, Lines 20-23).

It would be obvious to one of ordinary skill in the art at the time the invention was made to further combine the teachings of Waldeck and Onda *et al.* with those of Soe *et al.* and

Edwardson *et al.* The Waldeck patent shows that etherification processes of cellulose comprising reaction with sodium hydroxide and chloracetic acid is known in the prior art. The Onda *et al.* patent teaches a method of producing low-substituted cellulose ethers in which process steps previously disclosed in the prior art may be used in conjunction with the neutralization steps disclosed therein. It is the position of the examiner that process variables including reaction times, quantities of components, and concentration of reagents may be optimized by one of ordinary skill in the art to suit various purposes. The Soe *et al.* patent states that the use of low-substituted carboxymethylcellulose is preferred for the disclosed invention. Therefore, one of ordinary skill in the art would seek to find methods of producing such a low-substituted cellulose ether in order to carry out the best mode of the invention described in the Soe *et al.* patent. The combined teachings of Waldeck and Onda *et al.* are such methods of production. From there, further treatment of the material with carbodiimide according to Edwardson *et al.* may be carried out for the reasons described above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Patent Examiner
Art Unit 1615

sjo
September 4, 2002

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